



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2022-0867; FRL 9655-01-OCSP]

RIN 2070-AL10

Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Toxic Substances Control Act (TSCA), EPA is proposing a significant new use rule (SNUR) for those per- and poly-fluoroalkyl substances (PFAS) that have not been manufactured (including imported) or processed for many years and are consequently designated as inactive on the TSCA Chemical Substance Inventory. PFAS are a group of chemicals that have been used in industry and consumer products since the 1940s because of their useful properties, such as water and stain resistance. Many PFAS break down very slowly and can build up in people, animals, and the environment over time. Exposure at certain levels to specific PFAS can adversely impact human health and other living things. Persons subject to the SNUR would be required to notify EPA at least 90 days before commencing any manufacture (including import) or processing of the chemical substance for a significant new use. Once EPA receives a notification, EPA must review and make an affirmative determination on the notification, and take such action as is required by any such determination before the manufacture (including import) or processing for the significant new use can commence. Such a review will assess whether the use may present unreasonable risk to health or the environment and ensure that EPA can prevent future unsafe environmental releases of the PFAS subject to this SNUR.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0867, using the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Bethany Masten, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8803; email address: TSCA_PFAS@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import), process, or distribute in commerce chemical substances and mixtures. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- NAICS 324—Petroleum and Coal Product Manufacturing;
- NAICS 221210—Natural Gas Distribution;
- NAICS 236220—Commercial and Institutional Building Construction;
- NAICS 324—Petroleum and Coal Product Manufacturing;

- NAICS 32419—Petroleum Lubricating Oil and Grease Manufacturing;
- NAICS 325—Chemical Manufacturing;
- NAICS 325120—Industrial Gas Manufacturing;
- NAICS 325180—Other Basic Inorganic Chemical Manufacturing;
- NAICS 325199—All Other Basic Organic Chemical Manufacturing;
- NAICS 325211—Plastics Material and Resin Manufacturing;
- NAICS 325212—Synthetic Rubber Manufacturing;
- NAICS 325220—Artificial and Synthetic Fibers and Filaments Manufacturing;
- NAICS 325320—Pesticide and Other Agricultural Chemical Manufacturing;
- NAICS 325411—Medicinal and Botanical Manufacturing;
- NAICS 325412—Pharmaceutical Preparation Manufacturing;
- NAICS 325612—Polish and Other Sanitation Good Manufacturing;
- NAICS 325613—Surface Active Agent Manufacturing;
- NAICS 325998—All Other Miscellaneous Chemical Product and Preparation

Manufacturing;

- NAICS 326113—Unlaminated Plastics Film and Sheet (except Packaging)

Manufacturing;

- NAICS 327910—Abrasive Product Manufacturing;
- NAICS 333999—All Other Miscellaneous General Purpose Machinery Manufacturing;
- NAICS 334511—Search, Detection, Navigation, Guidance, Aeronautical, and Nautical

System and Instrument Manufacturing;

- NAICS 336111—Automobile Manufacturing;
- NAICS 423120—Motor Vehicle Supplies and New Parts Merchant Wholesalers;
- NAICS 423420—Office Equipment Merchant Wholesalers;
- NAICS 423510—Metal Service Centers and Other Metal Merchant Wholesalers;
- NAICS 423740—Refrigeration Equipment and Supplies Merchant Wholesalers;

- NAICS 423990—Other Miscellaneous Durable Goods Merchant Wholesalers;
- NAICS 424690—Other Chemical and Allied Products Merchant Wholesalers;
- NAICS 424720—Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals);

- NAICS 424950—Paint, Varnish, and Supplies Merchant Wholesalers;
- NAICS 441110—New Car Dealers;
- NAICS 447190—Other Gasoline Stations;
- NAICS 551112—Offices of Other Holding Companies; and
- NAICS 562—Waste Management and Remediation Services.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)); (see also 40 CFR part 707, subpart D and 40 CFR 721.20).

If you have any questions regarding the applicability of this action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2) (see Unit IV).

Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA further provides that such manufacturing (including import) or processing may not commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

TSCA section 26(c) (15 U.S.C. 2625(c)) authorizes EPA to take action under other sections of TSCA with respect to categories of chemical substances.

C. What action is the Agency taking?

To protect health and the environment and ensure EPA review of significant new uses of certain PFAS, EPA is proposing a SNUR for those PFAS that are currently on the TSCA Inventory but which have not been actively manufactured (including imported) or processed in the U.S. since 2006 and are consequently designated as inactive on the TSCA Chemical Substance Inventory. PFAS are a group of synthetic chemicals that have been in use since the 1940s and are still used in a wide range of consumer products and industrial applications. This proposed action is part of the comprehensive approach outlined in the Agency's "PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024" to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment (Ref. 1).

If a chemical is on the TSCA Chemical Substance Inventory ("TSCA Inventory"), that chemical substance is considered an "existing" chemical substance in U.S. commerce. In some instances, the chemicals listed on the TSCA Inventory have not been actively manufactured for many years and are designated as "inactive" on the TSCA Inventory. The chemical substances for which EPA is proposing a SNUR are those PFAS that are both currently designated as

inactive on the TSCA Inventory and not subject to an existing SNUR, including the existing SNURs cited at 40 CFR 721.9582 and 721.10536. This category of PFAS chemical substances (“inactive PFAS”) is described further in Unit II.A. There are 330 inactive PFAS that are not subject to an existing SNUR. The specific chemical identities for 30 of these substances that have been claimed as CBI have generic names (the nonconfidential substitute for the specific chemical name) that do not contain “fluor” or “fluorine.”

The proposed significant new uses are manufacture (including import) or processing for any use. The proposed significant new uses EPA has identified in this unit are based on reasonably available information that indicates that these uses are not ongoing at the time of this proposed rule; according to the TSCA Inventory they are inactive, meaning that those chemicals have not been manufactured (including imported) or processed in the United States since June 21, 2006. EPA is requesting public comment on this proposal, and specifically on the Agency’s description of the significant new uses for the chemicals identified, including specific documentation of ongoing uses, if any.

This proposed SNUR would require persons that intend to manufacture (including import) or process any of these chemicals for a significant new use, consistent with the requirements at 40 CFR 721.25, to notify EPA at least 90 days before commencing such manufacture (including import) or processing. Once EPA receives a notification, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury to health or the environment, or take such regulatory action as is associated with an alternative determination, before the manufacture or processing for the significant new use could commence.

D. Why is the Agency taking this action?

As noted previously, this action is part of the comprehensive approach outlined in the Agency’s “PFAS Strategic Roadmap: EPA’s Commitments to Action 2021-2024” to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact

human health and the environment (Ref. 1). When TSCA was first passed, thousands of chemicals, including some PFAS, were grandfathered in under the statute and allowed to remain in commerce without additional EPA review. Before TSCA was amended in 2016, EPA completed formal reviews on only about 20% of new chemicals and had no authority to address new chemicals about which the Agency lacked sufficient information, which is part of the reason why many chemicals, including PFAS, were allowed into commerce without a complete review. Under the new law, the agency has to formally review the safety of 100% of new chemicals before they are allowed into commerce. One common characteristic of concern of PFAS is that many break down very slowly and can build up in people, animals, and the environment over time. This proposed SNUR is necessary to ensure that EPA receives timely advance notice of any future manufacturing (including import) or processing of inactive PFAS for new uses that may produce changes in human or environmental exposures, and to ensure that an appropriate determination (relevant to the risks associated with such manufacturing (including import), processing, distribution in commerce, use and disposal) has been issued prior to the commencement of such manufacturing (including import) or processing. The proposed action is necessary to ensure that manufacturing (including importing) or processing for the significant new use cannot proceed in the event that EPA determines that: (1) The significant new use presents an unreasonable risk under the conditions of use (without consideration of costs or other nonrisk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA); (2) The information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use; (3) In the absence of sufficient information, the manufacture (including import), processing, distribution in commerce, use, or disposal of the substance, or any combination of such activities, may present an unreasonable risk (without consideration of costs or other nonrisk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA), or (4) There is sufficient potential for

environmental release or human exposure (as defined in TSCA section 5(a)(3)(B)(ii)(II)). In order for manufacturing (including importing) or processing for the significant new use to proceed after EPA has made one of the 4 determinations described above, EPA must take actions under TSCA sections 5(e) or 5(f) to protect health and the environment.

With respect to the chemical substances listed in the proposed regulatory text, all manufacturing (including importing) and processing ceased on or before June 21, 2006, as discussed in Unit II.A. Any new manufacturing (including importing) or processing for any use following that date would thus significantly change the volume of production, which is believed to be negligible.

EPA is proposing to exempt from the notice requirement PFAS present as impurities, certain byproducts, and the importing or processing of inactive PFAS-containing articles defined at 40 CFR 721.45(d) through (f) because notification for the commercial activity designation (as active or inactive) on the TSCA Inventory is not required for such substances (see 40 CFR 710.27(a)).

The rationale and objectives for this proposed SNUR are further explained in Unit III.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers (including importers) and processors of the chemical substances included in this proposed rule. This analysis (Ref. 2), which is available in the docket, is discussed in Unit IX., and is briefly summarized here.

In the event that a SNUN is submitted, costs are estimated to be approximately \$26,737 per SNUN submission for large business submitters and \$11,047 for small business submitters. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country, which is estimated to be approximately \$106 per notification.

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through <https://www.regulations.gov> or email. Clearly mark the part or all the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI, and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

3. *Comments about ongoing uses of inactive PFAS.* EPA welcomes comment on all aspects of this proposed rule. In providing comments on an ongoing use of inactive PFAS, it would be helpful if you provide sufficient information for EPA to substantiate any assertions of an ongoing use.

II. Chemical Substances Subject to this Proposed Rule

A. What chemicals substances are subject to this proposed SNUR?

This proposed SNUR would apply to chemical substances designated as inactive on the TSCA Inventory that are also PFAS. However, EPA is proposing that inactive PFAS already subject to a significant new use rule, including but not limited to the significant new use rules cited at 40 CFR 721.9582 and 721.10536, are not subject to notice requirements under this section to avoid potential redundancies or conflicts between the SNURs. Inactive chemical substances on the TSCA Inventory are those chemical substances that have not been manufactured (including imported) or processed since June 21, 2006.

TSCA section 8(b) requires EPA to compile, keep current and publish a list of each chemical substance that is manufactured (including imported) or processed in the United States for uses under TSCA. Also called the “TSCA Inventory” or simply “the Inventory,” it plays a

central role in the regulation of most industrial chemicals in the United States. TSCA also requires EPA to designate each chemical substance on the TSCA Inventory as either “active” or “inactive” in U.S. commerce (15 USC 2607(b)(4)(A)). To accomplish that, EPA finalized a rule requiring industry to notify the Agency of each chemical substance manufactured (including imported) or processed in the U.S. over a 10-year period ending on June 21, 2016 (with certain exemptions from reporting at 40 CFR 710.27(a)) (Ref. 3). This reporting was completed on October 5, 2018 and, combined with data received under the Chemical Data Reporting (CDR) rule in 2012 and 2016, was used to designate each chemical substance on the TSCA Inventory as active or inactive in U.S. commerce. Starting August 5, 2019, manufacturers (including importers) and processors have been required to notify EPA before reintroducing inactive substances into U.S. commerce. Moving a chemical substance from an inactive designation to an active designation on the TSCA Inventory does not require review by EPA, only that EPA be notified via a Notice of Activity form.

EPA has published several SNURs covering certain perfluoroalkyl sulfonates (67 FR 11007, March 11, 2002 (FRL-6823-6); 67 FR 72854, December 9, 2002 (FRL-7279-1); 72 FR 57222, October 9, 2007 (FRL-8150-4); 78 FR 62443, October 22, 2013 (FRL-9397-1)) and long-chain perfluoroalkyl carboxylate chemical substances (85 FR 45124, July 27, 2020 (FRL-10010-44)), that use a structural definition, as opposed to a discrete list, for the PFAS covered in the SNURs. Additionally, other SNURs (85 FR 45124, July 27, 2020 (FRL-10010-44; 58 FR 27944, May 12, 1993 (FRL-4077-7), as amended at 58 FR 34204, June 23, 1993 (FRL-4587-1)) and the polymer exemption rule for pre-manufacture notices (PMNs) (60 FR 16316-16336, March 29, 1995 (FRL-4929-8)) define covered PFAS polymers using structural definitions (40 CFR 723.250)). Other scientific and regulatory bodies such as the Organization of Economic Cooperation and Development (OECD) (Ref. 4) have defined PFAS using various structural definitions. Thus, there is precedent for using a structural definition both for TSCA rules and for actions addressing PFAS. EPA is proposing to adopt a structural definition for this rule based, in

part, on this history of using structural definitions to establish the scope of chemical substances covered by a SNUR.

For the purposes of this proposed SNUR, the definition of “PFAS” includes chemicals that contain at least one of these three structures:

- $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons;
- $R-CF_2OCF_2-R'$, where R and R' can either be F , O , or saturated carbons; or
- $CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons.

While this proposed definition was developed to focus on substances most likely to be persistent in the environment while excluding those substances that are “lightly” fluorinated (*i.e.*, the molecule only contains unconnected CF_2 or CF_3 moieties), EPA acknowledges that substances that are not fully fluorinated may still be persistent in the environment, as the persistence of organofluoro compounds is more related to the density of C-F bonds within the molecule than to the existence of fully fluorinated carbons. For this SNUR, the proposed definition’s R group requirements do not include substances that only have a single fluorinated carbon, or unsaturated fluorinated moieties (*e.g.*, fluorinated aromatic rings and olefins), which are more susceptible to chemical transformation than their saturated counterparts, and therefore, are less likely to persist in the environment (Ref. 5). As such, EPA has determined that, for the purpose of this proposed rule, the definition does not include substances that only have a single fluorinated carbon or unsaturated fluorinated moieties.

EPA notes that this definition may not be identical to other definitions of PFAS used within EPA or by other domestic or international organizations. The term “PFAS” has been used broadly for varying research and/or regulatory needs. Various EPA programs may have distinct needs or purposes from this proposed SNUR, and therefore, different definitions of the term “PFAS” may be appropriate for other purposes. EPA does not have one Agency-wide definition of PFAS. For example, a definition from EPA’s Office of Water might focus on PFAS that have been detected in water, whereas a definition for TSCA might be one for PFAS that are expected

the be manufactured and processed for uses subject to TSCA. The Agency notes that this perspective, that different entities may have very different needs and no single PFAS characterization or definition meets all needs, is shared by other organizations, including the OECD (Ref. 4). EPA seeks comment on whether the above definition of PFAS is the most appropriate definition for this SNUR and acknowledges that there may be other rules or programs that apply different definitions to meet their own needs.

Chemical substances that fall within the scope of this proposed definition of PFAS encompass chemical substances that meet the structural definitions used in existing SNURs covering PFAS. However, the proposed regulatory text clarifies that PFAS subject to an existing SNUR would be excluded from this proposed SNUR. The Agency is proposing to exclude these substances from the scope of this proposed rule to avoid potential redundancies or conflicts between the SNURs. Such conflicts may arise because of chemical or use-specific exemptions from the existing significant new uses or because EPA had a reason to lift general exemptions from an existing SNUR that would still apply under this proposed SNUR.

The chemical substances for which EPA is proposing a SNUR are the 330 PFAS that are both currently designated as inactive on the TSCA Inventory and not subject to an existing SNUR. The specific chemical identities for 30 of these substances that have been claimed as CBI have generic names (the nonconfidential substitute for the specific chemical name) that do not contain “fluor” or “fluorine.” EPA is providing a list of the 300 inactive PFAS that do not mask “fluor” or “fluorine” in the generic name in the public docket for this proposed rule (Ref. 6). Because EPA is proposing to use a structural definition of PFAS for this SNUR, EPA need not take additional steps to ensure that the SNUR lists the 30 inactive PFAS that are not subject to an existing SNUR and whose generic names do not contain “fluor” or “fluorine”. The specific chemical identities of these substances have been claimed as CBI, and their generic names are the nonconfidential substitute for the specific chemical name that is treated as confidential. TSCA section 14(c)(1)(C) requires that generic names describe the chemical structure of the

chemical substance as specifically as practicable while protecting those features of the chemical structure that are claimed as confidential; and the disclosure of which would be likely to cause substantial competitive harm. Generic names are intended to reveal information about the chemical identity while masking those structural elements that are confidential. The lack of “fluor” or “fluorine” in a generic name masks that the chemical substance is a PFAS and information masked by a generic name is considered to be subject to a CBI claim. Therefore, listing the generic names of these substances on a list of PFAS would disclose structural information for these substances that has been claimed CBI. As a courtesy, EPA is also providing a list of 300 inactive PFAS that do not mask “fluor” or “fluorine” in the generic name in the public docket for this proposed rule (Ref. 6).

EPA seeks comment on whether the Agency should take further action to list out in the regulation either the specific chemical identity or generic name of all of the chemicals that fall within the scope of the proposed SNUR, including those with generic names that mask that the chemical substance as PFAS, since this proposed rule covers a specific list of substances. EPA describes two approaches that it could take to make such a list available below and seeks public input on each such approach.

First, EPA could determine that there are no applicable CBI claims for the generic names of the masked PFAS substances using the process described in 40 CFR 2.204(c). In other words, EPA could use that process to determine that the limited structural information that would be disclosed by identifying substances whose generic names do not include “fluor” or “fluorine” as PFAS is not CBI. EPA proposes making a good faith effort to identify and contact the original submitters of each such PFAS and/or document that EPA cannot find a successor entity to a submitter that does not continue to operate, then determining that the generic names that do not include “fluor” or “fluorine” are not entitled to confidential treatment under 40 CFR 2.204(c)(3).

Alternatively, EPA could use the process under TSCA section 14(d)(7) and 40 CFR 2.306(i)/2.301(g)(2), whereby the Agency may disclose information claimed CBI if the

Administrator determines that disclosure is relevant in a proceeding under TSCA and the disclosure preserves confidentiality to the extent practicable without impairing the proceeding. Under this alternative, EPA would not disclose the specific chemical identity as part of the rulemaking. Rather, EPA would list the generic names that lack fluor or fluorine, disclosing that the chemical is a PFAS. EPA believes this is a limited form of disclosure that would be consistent with TSCA section 14(d)(7).

B. What are the uses and production volumes of inactive PFAS?

As discussed previously, the term inactive PFAS refers to PFAS that EPA designated as “inactive” in U.S. commerce on the TSCA Inventory (15 USC 2607(b)(4)(A)). Starting August 5, 2019, manufacturers (including importers) and processors have been required to provide notice to EPA to change the commercial activity designation from inactive to active before using a chemical substance designated as inactive on the TSCA Inventory for a nonexempt commercial purpose (Ref. 3). The Agency has not received such notifications for any of the PFAS currently designated as inactive on the TSCA Inventory. This indicates that all such PFAS, which include the PFAS covered by this proposed SNUR, are no longer being manufactured (including imported) or processed for any nonexempt uses in the United States. EPA acknowledges that the reporting of commercial activity under the TSCA Inventory Notification (Active-Inactive) Requirements Rule (“Active-Inactive rule”) was not required for several activities, including but not limited to, the import or processing of a chemical substance as part of an article (40 CFR 710.27(a)(2)) and the manufacturing or processing of a chemical substance in small quantities solely for research and development (40 CFR 710.27(a)(1)). Thus, there may be ongoing uses of inactive PFAS for these exempt activities. These uses would be exempt from this proposed inactive SNUR pursuant to the general SNUR exemptions at 40 CFR 721.45. The Agency solicits comment on any ongoing activities exempt from the Active-Inactive Rule that entities believe would not be covered by the general SNUR exemptions. The Agency expects to receive additional information about any ongoing use of PFAS in processed or imported articles as part

of the separate TSCA section 8(a)(7) PFAS reporting rule that was proposed on June 28, 2021 (June 28, 2021, 86 FR 33962), once it is finalized, and EPA may consider making inapplicable the exemption for articles in the future, as discussed in Unit X.

The Active-Inactive Rule also includes an exemption from notification for the manufacturing or processing of a chemical substance as described in 40 CFR 720.30(g) or (h) (40 CFR 710.27(a)(3)). Relevant to this proposed rule, the exemption at 40 CFR 720.30(h) covers “[a]ny byproduct which is not used for commercial purposes.” Thus, there may be inactive PFAS that were not reported under the Active-Inactive Rule because they were only manufactured or processed as byproducts that are not used for commercial purposes. There is no such broad exemption for byproducts in EPA’s general SNUR regulations at 40 CFR 721.45. Rather, EPA has only exempted byproducts from SNUR notification requirements in the limited circumstances where:

[t]he person manufactures, imports, or processes the substance only as a byproduct which is used only by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes.
40 CFR 721.45(e).

Therefore, without an exemption in the general regulations or in the proposed regulatory text, manufacturing or processing of the inactive PFAS as a byproduct would be a significant new use. EPA solicits comment on any ongoing manufacturing or processing of inactive PFAS subject to this SNUR as a byproduct and whether to include a broader exemption for manufacturing or processing as a byproduct in this inactive PFAS SNUR.

C. What are the potential routes and sources of exposure to inactive PFAS?

Due to their widespread use and persistence in the environment, most people in the United States have been exposed to PFAS. Biological sampling has discovered the presence of certain PFAS in fish and in fish-eating birds across the United States and in locations in Canada, Sweden, and the South Pacific. The wide distribution of the chemicals in high trophic levels is strongly suggestive of the potential for bioaccumulation and/ or bioconcentration. Based on

currently available information, EPA believes that in addition to persistence, the length of the perfluorinated chain may also have an effect on bioaccumulation and toxicity, which are characteristics of concern for these chemicals (Ref. 7). EPA expects that there are likely limited potential routes and sources of exposure to the inactive PFAS covered by the proposed SNUR because these substances have not been manufactured or processed for nonexempt uses in the United States since 2006. However, exposure may be possible because some PFAS are known to persist in the environment and have been shown to bioaccumulate in wildlife and humans (Refs. 7 and 8).

III. Rationale and Objectives

A. What is the rationale?

When TSCA was first passed, thousands of chemicals, including some PFAS, were grandfathered in under the statute and allowed to remain in commerce without additional EPA review. Before TSCA was amended in 2016, EPA completed formal reviews on only about 20% of new chemicals and had no authority to address new chemicals about which the Agency lacked sufficient information, which is part of the reason why many chemicals, including PFAS, were allowed into commerce without a complete review. Under the new law, the agency has to formally review the safety of 100% of new chemicals before they are allowed into commerce. On October 18, 2021, EPA issued the “PFAS Strategic Roadmap: EPA’s Commitments to Action 2021-2024” (Ref. 1). This proposed action is part of a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment. In the Roadmap, EPA committed to considering how to apply TSCA section 5(a)(2) authority to help address abandoned uses of PFAS as well as future uses of PFAS designated as inactive on the TSCA Inventory.

In the absence of a SNUR, manufacturing (including importing) or processing for the significant new uses proposed in this rule may begin at any time after a manufacturer submits a Notice of Activity under section 8 of TSCA and the substance becomes “active” on the TSCA

Inventory; EPA would not be provided prior notice under section 5 or an opportunity to review and address potential risks associated with the proposed new use. EPA believes that the manufacture (including import) or processing for any use of inactive PFAS would increase the magnitude and duration of exposure to humans and the environment to these chemicals that are persistent and bioaccumulate. Given the concerns described in Unit II., EPA believes that notification and EPA's required review are warranted for these chemicals prior to their potential reintroduction into commerce.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. If a person decides to begin manufacturing (including importing) or processing any of these chemicals for the use, the notice to EPA allows the Agency to evaluate the use according to the specific parameters and circumstances surrounding the conditions of use at the time it receives such a notification.

B. What are the objectives?

Based on the considerations in Unit III.A., EPA wants to achieve the following objectives with regard to the significant new use(s) of inactive PFAS that are designated in this proposed rule:

1. EPA would receive notice of any person's intent to manufacture (including import) or process the chemical substances for the described significant new use before that activity begins.
2. EPA would have an opportunity to review and evaluate information submitted in a SNUN before the notice submitter begins manufacturing (including importing) or processing the chemical substances for the described significant new use.
3. EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination under TSCA section 5 before the manufacture or processing for the significant

new use could commence.

IV. Significant New Use Determination

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing (including importing), processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of an inactive PFAS, EPA considered relevant information about the toxicity or expected toxicity of these substances, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. Since the manufacture (including import) and processing of inactive PFAS has been discontinued in the United States see Unit II., exposure will decrease over time. As such, EPA expects their presence in humans and the environment to decline over time. If any new uses of inactive PFAS were to resume after having been phased out, EPA believes that such uses could both change the type and form and increase the magnitude and duration of human and environmental exposure to the substances, constituting a significant new use. Based on consideration of the statutory factors discussed herein, EPA has preliminarily determined as significant new uses: manufacture (including import) or processing of inactive PFAS for any use.

V. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the proposed rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the proposed rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination under TSCA section 5 before the manufacturing (including importing) or processing for the significant new use could commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the *Federal Register*, a statement of EPA's finding.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the *Federal Register* of April 24, 1990 (55 FR 17376 (FRL-3658-5)),

EPA has decided that the intent of the TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. This rule is being proposed on **[INSERT PUBLICATION DATE IN THE *FEDERAL REGISTER*]**. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule.

Persons who begin commercial manufacturing (including importing) or processing of the chemical substances for a significant new use identified as of **[INSERT PUBLICATION DATE IN THE *FEDERAL REGISTER*]** would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until all TSCA prerequisites for the commencement of manufacturing (including importing) or processing have been satisfied. Consult the *Federal Register* document of April 24, 1990 (55 FR 17376 (FRL-3658-5)) for a more detailed discussion of the cutoff date for ongoing uses.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not usually require developing new information (*e.g.*, generating test data) before submission of a SNUN. There is an exception: development of information is required where the chemical substance subject to the SNUR is also subject to a rule, order, or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a section 4 test rule or order covering the chemical substance, persons are required to submit only information in their possession or control and to describe any other information known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters

include information that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture (including import), processing, distribution in commerce, use, or disposal. Potentially useful information includes physical-chemical property data and any information related to persistence, bioaccumulation, toxicity, and other characteristics that may help predict the impact of a chemical substance on health or the environment. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific information it believes may be useful in evaluating a significant new use.

Submitting a SNUN that does not include information sufficient to permit a reasoned evaluation may increase the likelihood that EPA will either respond with a determination that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use or, alternatively, that in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs and define the terms of any potentially necessary controls if the submitter provides detailed information on human exposure and environmental releases that may result from the significant new use of the chemical substances.

VIII. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what information may be useful in evaluating a significant new use notice. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form

No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at <https://www.epa.gov/chemicals-under-tsca>.

IX. Economic Analysis

A. What is the analysis for SNUNs?

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers (including importers) and processors of the chemical substances included in this proposed rule (Ref. 2). In the event that a SNUN is submitted, costs are estimated at approximately \$26,737 per SNUN submission for large business submitters and \$11,047 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$19,020 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business as defined at 13 CFR 121.201, a reduced user fee of \$3,300 (40 CFR 700.45(b)(1)). Additionally, these estimates reflect the costs and fees as they are known at the time this rule is promulgated. EPA's complete economic analysis is available in the public docket for this proposed rule (Ref. 2).

B. What is the analysis for export notifications?

Under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (*i.e.*, the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical covered in this proposed SNUR, as stated in the accompanying economic analysis of this proposed SNUR, the

estimated cost of the export notification requirement on a per unit basis is approximately \$106.

X. Regulatory Alternative Considered

EPA is also requesting public comment on the alternative of lifting the article exemption at 40 CFR 721.45(f). Under this alternative, the import and processing of articles containing inactive PFAS would be designated as a significant new use. EPA is not proposing this regulatory alternative, at this time, because it cannot currently determine whether or what types of articles containing PFAS covered by the definition in this proposed SNUR are ongoing or not. The import or processing of substances solely as part of articles is exempt from the notification requirements under the Active-Inactive Rule (Ref. 3). Consequently, the TSCA Inventory does not list chemical substances that are solely processed or imported as part of articles. The TSCA Inventory list of inactive PFAS therefore does not take into account ongoing importation or processing of PFAS in articles. EPA's SNURs are often amended, however, as ongoing uses of the chemical substances are phased out. Therefore, as EPA collects evidence and determines that the importing or processing of inactive PFAS into articles is no longer ongoing, EPA may consider whether to make inapplicable the articles exemption at 40 CFR 721.45(f).

EPA also seeks comment on the potential impact on firms that plan to import or process articles containing inactive PFAS, because, while not required by the proposed SNUR, these parties may take additional steps to determine whether inactive PFAS are part of the articles that they are considering to import or process.

XI. Scientific Standards, Evidence, and Available Information

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science, as applicable. These information sources supply information relevant to whether a particular use would be a significant new use, based on relevant factors including those listed under TSCA section 5(a)(2). As noted in Unit III., EPA's decision to promulgate a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with

that use.

The clarity and completeness of the data, assumptions, methods, quality assurance, and analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of this proposed significant new use rule, in Unit II. and in the references cited throughout the preamble of this proposed rule. EPA recognizes, based on the available information, that there is variability and uncertainty in whether any particular significant new use would actually present an unreasonable risk. For precisely this reason, it is appropriate to secure a future notice and review process for these uses, at such time as they are known more definitely. The extent to which the various information, procedures, measures, methods, protocols, methodologies or models used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for a significant new use rule.

XII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. "PFAS Strategic Roadmap: EPA's Commitment to Action 2021-2024." EPA-100-K-21-002, October 2021.

2. U.S. EPA. "Economic Analysis of the Proposed Significant New Use Rule Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory." January 2022.

3. U.S. EPA. TSCA Inventory Notification (Active-Inactive) Requirements; Final Rule, 82 FR 37520, August 11, 2017.

4. Organisation for Economic Co-operation and Development (OECD). “Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance.” July 9, 2021.

5. Buck, R. C., Korzeniowski, S. H., Laganis, E, and Adamsky, F. (2021). “Identification and classification of commercially relevant per-and poly-fluoroalkyl substances (PFAS).” *Integrated Environmental Assessment and Management*, 17, 1045-1055.

6. U.S. EPA. “List of Select Chemicals Subject to the Proposed Significant New Use Rule Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory.” January 2022.

7. Agency for Toxic Substances and Disease Registry (ATSDR). “Toxicological Profile for Perfluoroalkyls.” May 2021. Available from: <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>.

8. Evich, Marina G, Davis, Mary J.B., McCord, James P., Acrey, Brad, Awkerman, Jill A., Knappe, Detlef R.U., Lindstrom, Andrew B., Speth, Thomas F., Tebes-Stevens, Caroline, Strynar, Mark J., Wang, Zhanyun, Weber, Eric J., Henderson, Matthew W., Washington, John W. (2022). Per- and polyfluoroalkyl substances in the environment. *Science*. 375: 6580, 1-14.

XIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action under Executive Order 12866 (58 FR 51735, October 4, 1993) and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2070-0038 (EPA ICR No. 2702.01) and the information collection activities associated with export notifications are already approved under OMB control number 2070-0030 (EPA ICR No. 0795.16). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system.

C. Regulatory Flexibility Act (RFA)

I certify this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, EPA concludes that the impact of concern is any significant adverse economic impact on small entities, and the Agency is certifying that this proposed rule will not have a significant economic impact on a substantial number of small entities.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the proposed rule as a “significant new use.” By definition of the word “new” and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year (Ref. 2). EPA believes the cost of submitting a SNUN is relatively

small compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical and that the requirement to submit a SNUN generally does not have a significant economic impact.

Therefore, EPA believes that the potential economic impact of complying with this proposed SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only

to those regulatory actions that concern environmental health or safety risks that the Agency has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve any technical standards under section 12(d) of NTTAA, 15 U.S.C.272 note.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples because the Agency believes that the inactive PFAS included in this action are no longer being manufactured (including imported) or processed for any uses in the United States.

EPA believes that it is not practicable to assess whether this action is likely to result in

new disproportionate and adverse effects on people of color, low-income populations and/or Indigenous peoples because the Agency is not able anticipate which chemical substances and uses, if any, will be submitted for a significant new use notice under this action.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: January 17, 2023.

Michal Freedhoff,

Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons set forth in the preamble, it is proposed that 40 CFR chapter I be amended as follows:

PART 721-- SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add § 721.11777 to subpart E to read as follows:

§ 721.11777 Per- and Poly-fluoroalkyl chemical substances designated as inactive on the TSCA Inventory.

(a) *Definitions.* The definitions in § 721.3 apply to this section.

(b) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified in paragraphs (b)(1)(i) through (iii) of this section, designated as inactive on the TSCA Chemical Substance Inventory as of the date of publication of this proposed rule, are subject to reporting under this section for the significant new uses described in paragraph (b)(2) of this section.

(i) R-(CF₂)-CF(R')R'', where both the CF₂ and CF moieties are saturated carbons;

(ii) R-CF₂OCF₂-R', where R and R' can either be F, O, or saturated carbons; and

(iii) CF₃C(CF₃)R'R'', where R' and R'' can either be F or saturated carbons.

(2) The significant new uses for the chemical substances identified in paragraph (b)(1) of this section are: manufacture (including import) or processing for any use.

(c) *Chemical substances not subject to reporting.* The chemical substances already subject to a rule under this part, including § 721.9582, and § 721.10536, are not subject to reporting under this section.

(d) *Specific requirements.* The provisions of subpart A of this part apply to this section.